UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2272**
	)	**Master Docket No. 11 C 5468**
THEODORE JOAS and DARLENE JOAS,	)	
Plaintiffs,	)	
v.	)	**No. 13 C 9216**
ZIMMER, INC.,	)	**Judge Rebecca R. Pallmeyer**
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Defendant Zimmer Inc. manufactures knee implants, among other medical devices. Plaintiffs in this multidistrict litigation proceeding (MDL) are individuals whose native knees were replaced by Zimmer NexGen Flex knee implants during total knee replacement (TKR) surgery. They allege that they have suffered pain and loss of movement, and in some cases, have had to undergo revision surgeries, because the NexGen Flex device is prone to premature loosening.

The second case to be scheduled for a bellwether trial in this MDL was brought by Plaintiff Theodore Joas and his wife, Darlene Joas. Mr. Joas underwent revision surgery in 2014 because of loosening in the tibial component of his NexGen Flex implant, loosening that he alleges resulted from a defect in the implant's design. The first bellwether case—brought by Plaintiff Kathy Batty and her husband, Thomas Batty—went to trial roughly one year ago and resulted in a jury verdict for Zimmer. *See Batty v. Zimmer, Inc.*, No. 12 C 6279 [141]. In advance of the *Batty* trial, this court issued a number of rulings on evidentiary matters and on Zimmer's motion for summary judgment. *See, e.g.*, *In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.*, No. 11 C 5468, 2015 WL 3669933, at *1 (N.D. Ill. June 12, 2015) [hereinafter "*Batty* Opinion"] (ruling on motions to exclude testimony of two of plaintiff's experts, Dr. Thomas Brown and Dr. Joseph Fetto, and granting motion for summary judgment in part and denying it in part). In Joas's case, the parties have again filed a number of motions *in limine*, including requests from both sides to exclude testimony from certain of the other's expert witnesses, and Zimmer

has again moved for summary judgment on all counts.

In this opinion, the court addresses Zimmer's motion to exclude the testimony of Dr. Joseph Fetto [31] under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as well as Zimmer's motion for summary judgment [37]. Zimmer argues that Dr. Fetto's testimony should be excluded because his opinion regarding the cause of the loosening in Joas's tibial component is based on an unreliable methodology. Dr. Fetto employed a differential diagnosis, or "differential etiology," an accepted and well-established method for determining causation, but Zimmer argues that Dr. Fetto failed to apply the method correctly. In addition to its criticism of Dr. Fetto's testimony, Zimmer contends that Plaintiffs lack reliable expert testimony to establish that the design of the NexGen Flex knee was defective or that any alleged defect caused Joas's injury. Zimmer also argues that there was nothing inadequate about the warning contained in the device's package insert and that Plaintiffs have not shown that any change in Zimmer's warning would have prevented Joas's injury.

Plaintiffs respond that the biomechanical engineering testimony of Dr. Thomas Brown and the statistical analysis offered by Dr. David Madigan will provide a sufficient basis for the jury to conclude that the NexGen Flex contains a design defect. Further, they assert that Dr. Fetto's testimony, which is based on his examination of Joas and a review of his medical records, will establish that the implant's defective design was the cause of Joas's injury. In support of their failure-to-warn claims, Plaintiffs contend that Zimmer failed to warn about the risks of engaging in high-flexion (that is, bending the knee beyond 120 degrees) activities with the NexGen Flex knee and failed to provide adequate instructions to surgeons about the amount of cement required to affix the implant to the patient's bone. That Zimmer's warnings were inadequate and that improved warnings would have avoided Joas's injury are points so obvious, they insist, that no expert testimony is necessary to establish them.

For the reasons discussed below, the court concludes that, because Dr. Fetto failed to apply his stated methodology in a reliable manner, his testimony must be excluded. The court

also concludes that Plaintiffs have failed to present sufficient evidence to allow a jury to find for them on any of their claims. The court therefore grants Zimmer's motion for summary judgment on all counts.

BACKGROUND

In February 2008, at the relatively young age of 54, Joas underwent total knee replacement surgery because rheumatoid arthritis was causing persistent pain in his left knee. (Report of Dr. Joseph Fetto, re: Theodore Joas (July 22, 2016), Ex. B to Zimmer's Mem. in Supp. of Mot. to Exclude Test. of Dr. Joseph Fetto (hereinafter "Def.'s Fetto Mem.") [32-2], (hereinafter "Fetto Rep."), at 2.) Dr. Bryan Larson performed the surgery at Sacred Heart Hospital in Eau Claire, Wisconsin, and selected the Zimmer NexGen Flex knee implant that would replace Joas's native knee. (*Id.*) As the court has discussed previously, the NexGen Flex implant was designed to allow patients to achieve higher flexion than they could when using the "Standard" version of Zimmer's NexGen implant. *See Batty* Opinion, 2015 WL 3669933, at *2–*3.[1] At the time of his surgery, Joas weighed 202 pounds and stood five feet, seven inches tall, giving him a body mass index (BMI) of 31. (Dep. of Dr. Joseph Fetto, Ex. C to Def.'s Mem. in Supp. of Mot. to Excl. Testimony of Dr. Joseph Fetto [32-3] (hereinafter "Fetto Dep.), at 358:6–11.)

Joas's recovery from surgery went well, and he was eventually able to return to work for Pepsi Bottling Group, where his job required him to lift and carry heavy loads and to squat repetitively during the course of a day. (*Id.*) After returning to work, Joas continued to engage in physical therapy at home and also participated in other physical activities, including exercising on a stationary bicycle and recreational hunting, canoeing, and fishing. (*Id.*) At some point in 2011 or 2012, however, Joas again began to experience pain in his left knee. (*See* Dep. of Theodore Joas, Ex. L to Def.'s Mem. in Supp. of Mot. to Excl. Testimony of Dr. Joseph

[1] The court assumes familiarity with its summary judgment ruling in *Batty*, which contains diagrams and discussion of a total knee implant and of the NexGen Flex implant's particular components. *See Batty* Opinion, 2015 WL 3669933, at *2–*3.

Fetto [32-12] (hereinafter "Joas Dep.), at 200:1–11.) In August 2012, Dr. William Decesare ordered an x-ray and bone scan of Joas's knee, the results of which were consistent with aseptic loosening of the tibial component of Joas's implant. (Fetto Rep. at 2.) Joas then saw an orthopedic surgeon, Dr. Scott Cameron, who concurred with the diagnosis of aseptic loosening of the tibial component and performed a revision of that component in October 2014, again at Sacred Heart Hospital in Eau Claire. (*Id.*)

Plaintiffs contend that Joas's tibial component loosened because the design of the NexGen Flex causes premature loosening in TKR patients who engage in high-flexion activities following their surgeries, a risk about which Zimmer allegedly failed to warn. Plaintiffs' complaint alleged a host of claims: strict liability design defect, strict liability failure to warn, strict liability manufacturing defect, negligence, negligent misrepresentation, breach of express warranty, breach of implied warranty, violation of Wisconsin consumer protection law, unjust enrichment, and fraudulent concealment. (*See* Pls.' Approved Short Form Compl. [1] at 5–8.) Plaintiffs also alleged that Zimmer's wrongdoing supports an award of punitive damages. (*Id.* at 8.) Zimmer has moved for, and advanced arguments in support of, summary judgment on all counts, but Plaintiffs responded only to the arguments regarding design defect, failure to warn, negligence, and punitive damages. In support of their design defect and negligence claims, Plaintiffs offer the expert testimony of Dr. Brown, Dr. Madigan, and Dr. Fetto. In particular, Plaintiffs rely on the testimony of Dr. Brown and Dr. Madigan to support the contention that the NexGen Flex design predisposes the implant to tibial loosening, while Dr. Fetto's testimony is offered to establish that it was a defect in the NexGen Flex that caused Joas's loosening. Plaintiffs offer no expert testimony in support of their failure-to-warn claims. The court discusses the proposed testimony of Plaintiffs' experts below, before discussing the facts underlying Plaintiffs' failure-to-warn claims.

I. Dr. Brown's Proposed Expert Testimony

The court discussed Dr. Brown's biomechanical engineering opinions extensively in its

ruling on Zimmer's *Daubert* motion to exclude his testimony in *Batty*. *See Batty* Opinion, 2015 WL 3669933, at *7–*18. Over Zimmer's objections, the court permitted Dr. Brown to testify that the design of NexGen Flex predisposes the implant to femoral and tibial loosening. *Id.* Unlike in *Batty*, there is no evidence in this case that the femoral component of Joas's implant loosened, so the court will confine its discussion to Dr. Brown's theory of tibial loosening. Essentially, the theory of tibial loosening Dr. Brown presented in *Batty* is as follows: When individuals engage in high-flexion, weight-bearing activities (deep squatting, for example), there is the potential for significantly elevated loading to concentrate on the posterior (that is, the rear) surface of the tibial component. This high concentration of loading can then cause the tibial component to "rock" or "toggle," which could lead to loosening of the component, or "fixation interface failure," over time. *See id.* at *16; (Supp. Expert Report of Thomas Brown, Ex. A to Def.'s Mot. for Summ. J. [34-1] (hereinafter "Brown Supp. Rep."), at 1.) Patients who receive the NexGen Standard implant are unlikely to flex their knees to an angle greater than 130 degrees, Dr. Brown explains, because at that angle of flexion, the femoral bone would impinge on, or collide with, the tibial component. (*See* Expert Report of Thomas Brown, Ex. 3 to Pls.' Resp. to Zimmer's Second *Daubert* Mot. [121-1] (hereinafter "Brown Rep."), at 48.) The NexGen Flex, however, has a posteriorly extended femoral component, which allows patients who receive the implant to achieve an additional 25 degrees of flexion before "impingement" would occur. (*Id.* at 49.) Dr. Brown's initial expert report, prepared in advance of the *Batty* trial, criticized Zimmer for failing to conduct testing to compare the propensity for micro-motion under "worst-case scenarios" for the respective Standard and Flex designs; that is, Zimmer did not compare the micro-motion of the Standard knee's tibial component at its maximum flexion angle of 130 degrees with that of the Flex knee's tibial component at its maximum flexion angle of 155 degrees. (*Id.*) According to Dr. Brown's theory, the increased flexion in patients with Flex implants would cause increased loading forces on the posterior surface of the tibial component

as well as additional shifting of the force toward the component's posterior edge.[2] (*See* Brown Supp. Rep. at 1.)

In *Batty*, the court declined to exclude Dr. Brown's opinion regarding tibial loosening because Dr. Brown had reliably explained why the Flex design would be more prone to tibial loosening than would the Standard design under high flexion. *Batty* Opinion, 2015 WL 3669933, at *16. Although Dr. Brown did not conduct any tests to show that the Flex knee actually *would* be subject to increased micro-motion (and thus loosening) at high-flexion angles, the court noted that testing of an opinion is not a prerequisite for its admissibility. The court concluded that Dr. Brown was free to criticize Zimmer's internal testing and to infer what an alternative testing protocol would have revealed. *Id.* at *17. In the supplemental report that Dr. Brown recently submitted, he attempts to quantify the moment (that is, the product of the contact force and the distance of the femoral component's posterior translation, or shift) that would tend to cause toggling or micro-motion at various flexion angles. (*See* Brown Supp. Rep. at 6.) But in this supplemental report, and during his most recent deposition, Dr. Brown's clarification of his opinions casts doubt upon the court's previous conclusion that Dr. Brown could reliably infer that patients implanted with a Flex device, as opposed to a Standard device, actually would experience increased toggling and micro-motion of their tibial components. Though Dr. Brown's modeling did find toggle moment increases in the range of 30% to 60%-80% at various high-flexion angles, he conceded that without reliable interfacial stress data for the tibial components of Flex devices, "there is no way to formally quantify whether or not these levels of additional toggle moment demand would represent an unacceptable risk for fixation interface failure." (*Id.* at 7.) He opines that the increased toggle moments warrant serious concern and should have prompted Zimmer to investigate whether the toggle moment levels he has quantified would cause interface failure, but he admits that he has "no way of knowing"

[2] Dr. Brown also opines that loading on the tibial component's posterior ledge can lead to mechanical damage to the polyethylene insert that sits on the upper tray of the tibial component. (Brown Rep. at 44–47.) Plaintiffs in this case, however, do not argue that there was any damage to the polyethylene insert in Joas' implant.

what the results would have been, had Zimmer conducted the appropriate testing. (Dep. of Thomas Brown, Ex. B to Def.'s Mem. in Supp. of Second *Daubert* Mot. [34-2] (hereinafter "Brown Dep."), at 97:15–98:15.)

In both his initial expert report and his supplemental report, Dr. Brown discusses alternative implant designs. As mentioned above, Dr. Brown compared the NexGen Flex with the NexGen Standard and concluded that a patient's ability to achieve high flexion with the NexGen Flex knee could increase the risk of toggling, and thus loosening, of the implant's tibial component. But Dr. Brown concedes that "there seems little if any reason for concern about NexGen-Flex performance below the [range of 120 to 130 degrees]." (Brown Supp. Rep. at 6–7.) And if a patient were to engage in flexion above the range of 130 degrees, Dr. Brown admitted it would be safer for him or her to do so with a Flex implant than with a Standard implant. *See Batty* Opinion, 2015 WL 33669933, at *17 (citing Brown's deposition testimony from *Batty*). In his initial report, Dr. Brown also mentions that some of Zimmer's academic collaborators, including Dr. Peter Walker and Drs. Guoan Li and Harry Rubash, were concerned about the possibility of excessive posterior edge loading of the polyethylene insert but that Zimmer "opted not to implement specific design suggestions by Walker and Li and Rubash" in the NexGen Flex. (Brown Rep. at 31.) According to Brown, Zimmer eventually did implement "several of these changes," but in a different product. (*Id.*) The one design feature of that subsequent product that Dr. Brown mentions is the elimination of a required two-millimeter bone cut prior to implantation of the device (a design change that has no relevance to tibial loosening, according to Dr. Brown). (*Id.* at 38.) In his supplemental report, Dr. Brown also alludes to a specific design alternative conceived by Drs. Li and Rubash. The one paragraph in his report devoted to that design reads as follows:

> As early as 2001 or 2002, Drs. Li and Rubash had conceived an alternative to some of the key features of the then-existing form of the Zimmer Nexgen Flex device. In my opinion their design modification was biomechanically reasonable. They wrote to Zimmer suggesting that Zimmer implement that design modification. However, Zimmer did not do so. Incorporation of this proposed design change would have constituted an alternative to the then-existing NexGen Flex design.

(Brown Supp. Rep. at 7.)

II. Dr. Madigan's Proposed Expert Testimony

For purposes of this particular ruling, the court need not discuss Dr. Madigan's proffered opinions in great detail. Dr. Madigan is a statistician who conducted a meta-analysis of clinical trial studies involving patients with knee implants. (*See generally* Report of David Madigan, Ex. A to Def.'s Mem. in Supp. of Mot. to Excl. Testimony of Dr. David Madigan [36-1].) Based on his analysis, Dr. Madigan concluded that Zimmer's Flex implants likely cause a higher risk of revision than standard devices. (*Id.* at 12.) In particular, by focusing on 10-year studies, he concluded that the probability that Flex implants cause a higher risk of revision than standard devices approaches 100%, and that the probability that Flex implants cause a higher risk of aseptic loosening than standard devices is 96.8%. Zimmer charges that Dr. Madigan's conclusions are based on an unreliable methodology, but for purposes of this opinion, the court assumes that his testimony would be admissible. The court does note, however, that although Dr. Madigan offers an opinion that Flex implants have a higher risk of revision and of aseptic loosening than standard devices, he does not offer any opinion about (1) the absolute rate at which Flex devices are likely to loosen or to be revised over a particular time period or (2) any aspect of the Flex design that might cause the alleged higher risk of revision relative to the standard device.

III. Dr. Fetto's Proposed Expert Testimony

In the *Batty* trial, Dr. Fetto submitted a general report detailing his opinions on the Zimmer Flex knee, as well as a report specific to Ms. Batty's knee replacement. In this case, Dr.

Fetto has submitted a report on Joas's knee replacement. Dr. Fetto's case-specific *Joas* report incorporates the general report he prepared for the MDL as a whole.

A. The Court's Ruling on Dr. Fetto's Opinions in *Batty*

In *Batty*, the court allowed Dr. Fetto to testify to opinions on biomechanics, but excluded opinions regarding (1) risks of component loosening, (2) the adequacy of Zimmer's warnings, and (3) the adequacy of Zimmer's pre-market testing. *Batty* Opinion, 2015 WL 3669933, at *1. Some of Dr. Fetto's opinions that were excluded in *Batty*, regarding Zimmer's warnings and pre-market testing, are not applicable in this case, but his opinions on component loosening are relevant. In *Batty*, the court "[could not] discern any reliable methodology supporting Dr. Fetto's opinions regarding the design defect, [or] the risk of aseptic loosening . . . and conclude[d] that those opinions must be excluded." *Id.* at *19.

Specifically, the court declined to admit Dr. Fetto's opinion that the design of the Zimmer knee replacement "forces loading onto the posterior margin of the tibial component and reduces overall contact area between the femoral and tibial components." *Id.* at *21 (internal citations omitted). Dr. Fetto asserted that this posterior loading "produces a lift-off stress on the front of the tibial component," which "strains the bond between the tibial component and the tibial bone." *Id.* (internal citations omitted). The court acknowledged that Dr. Fetto cited evidence showing a higher revision rate for Zimmer high flex knees, but concluded that Dr. Fetto did not "sufficiently explain[] why he sees a link between the higher revision rates and the evidence of posterior loading." *Id.* at *22. The report he offered in *Batty* offered several explanations why eccentric loading causes high-flex components to loosen. At least two of these opinions are resurrected in Dr. Fetto's report on Joas. First, he again opines that high flexion causes greater forces pulling the bone and component apart: "bonds between the component and bones . . . are susceptible to 'tensile loading,' that is, forces that pull the bone and component apart from one another." *Id.* at *23. Additionally, he asserts "that if testing shows lift-off of the polyethylene tray from the tibial baseplate, that lift-off implies that the forces are sufficient to lift the tibial baseplate

from the bone[.]" *Id.* Both of these opinions were excluded because Dr. Fetto did not explain how the studies he cited supported this conclusion. *Id.* at *23–27.

Furthermore, the court in *Batty* pointed out that Dr. Fetto did not describe "why the Zimmer high-flex *design*, as opposed to high flexion generally, creates an increased risk of posterior edge loading." *Id.* at *22 (emphasis in original). The court concluded: "In sum, Dr. Fetto has not sufficiently explained how he reached the conclusion that Zimmer's designs cause aseptic loosening of the tibial component[,]" because "he has failed to connect the dots in a way that enables the court to adequately examine the bases for his conclusions and conduct a reliability analysis." *Id.* at *32. Consequently, Dr. Fetto's opinions that Zimmer's high-flex design increased the risk of component loosening were excluded. *Id.* at *32.

B. Dr. Fetto's Report on Joas

The parties agree that the court's rulings regarding the admissibility of Dr. Fetto's opinions in *Batty* also apply in this case. (Tr. of Aug. 26, 2016 Hr'g, Ex. E to Def.'s Fetto Mem. [32-5], at 15:13–22.) Dr. Fetto has submitted a new report specific to Joas's tibial component loosening. In this new report, Dr. Fetto conducts a differential etiology, which purports to consider all reasonable potential causes of an ailment and systematically rule out causes one by one.[3] (Fetto Rep. at 3.) "[I]n a differential etiology, the doctor rules in all the potential causes of a patient's ailment and then by systematically ruling out causes that would not apply to the patient, the physician arrives at what is the likely cause of the ailment."[4] *Myers v. Illinois Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). To support his etiology, Dr. Fetto reviewed Joas's

[3] Dr. Fetto calls this methodology a "differential diagnosis," while Zimmer calls it a "differential etiology." (Fetto Rep. 3; Zimmer's Reply in Supp. of its First Daubert Mot. to Exclude Test. of Dr. Joseph Fetto [126] (hereinafter "Def.'s Fetto Reply"), at 1.) "'Differential diagnosis' actually refers to a method of diagnosing an ailment, not determining its cause. 'Differential etiology,' on the other hand, is a causation-determining methodology." *Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 705 (7th Cir. 2015) (citing *Myers v. Illinois Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010)).

[4] Dr. Fetto employs the same definition: "With a differential diagnosis, all reasonable possibilities should be ruled out." (Fetto Rep. 3.)

medical records, radiologic images, depositions of Joas and his treating doctors, and Joas's explanted device. (Fetto Rep. at 1, 7–8.) Dr. Fetto also interviewed Joas twice and conducted a physical exam and medical history. (*Id.* at 1.)

Dr. Fetto begins by determining which causes to rule *in*. Dr. Fetto's list of potential causes included: "trauma, medical comorbidities,[5] infection, particulate debris, surgical error, problems with the cement, and mechanical causes." (*Id.* at 3.) Dr. Fetto also rules in "patient factors" such as excessive weight, poor quality bone, or excessive activities. (*Id.*) Although he notes that "polyethylene[6] wear that in turn causes microscopic particulate debris which causes an immunologic reaction in the bone," is a potential cause of loosening, he apparently does not rule that in because "Dr. Cameron[, who performed Joas's revision surgery,] testified that there was not a dramatic amount of wear debris." (*Id.* at 2.)

Second, Dr. Fetto rules *out* causes that he opines were not the cause of Joas's component loosening. He reviewed "the records provided and the depositions provided" and found no evidence of comorbidities, infection, or poor or improper surgical technique. (*Id.* at 3–4.) He also finds no "evidence of improper rehabilitation or level of activity following his surgical procedures[.]" (*Id.* at 4.) Second, he opines that Joas engaged in high-flexion activities, but that they were not "abusive." (*Id.* at 5.) Third, Dr. Fetto states that he found no evidence of bone problems, metabolic disorders, or other medical conditions. (*Id.* at 6.) Finally, he states that he "considered [Joas's] medication history, including his rheumatoid arthritis medications, and did not see anything in the medical records, surgical reports or diagnostic imaging, that would suggest they contributed to the aseptic loosing." (*Id.* at 6.) As a result, Dr. Fetto concludes "[t]his leaves only mechanical sources of failure related to the specific design of the implant Joas received to be considered." (*Id.* at 4.)

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[5] Dr. Fetto lists the examples of diabetes, smoking, or vascular conditions. (Fetto Rep. at 3.)

[6] A polyethylene surface is the point of contact between the femoral component and the tibial component. *Batty* Opinion, 2015 WL 3669933, at *8 n.9.

Having concluded that this final cause could not be ruled out, Dr. Fetto devotes the remainder of the report to explaining why the design defect caused Joas's knee replacement failure. (*Id.* at 4–6.) Dr. Fetto opines that Joas's knee implant failed for the same reasons stated in his general report. According to Dr. Fetto, as a replaced knee bends and achieves greater degrees of flexion, the following occurs: First, external rotation of the femur causes posterior translation (that is, shifting back) of the lateral femoral condyle.[7] (*Id.* at 4.) Second, posterior migration of the femoral component causes asymmetric loading of the tibial plateau and the femoral component. (*Id.*at 4.) Third, asymmetric contact of the femoral condyles, or lift-off, causes excessive and asymmetric loading. (*Id.*) Dr. Fetto concludes that this asymmetric loading places undue stress on the tibia, which he opines is what happened to Joas. (*Id.*) He concludes that the asymmetric loading "is evident in Joas's case, which demonstrated aseptic loosening beneath the tibial component." (*Id.*) Dr. Fetto notes that "[t]hese findings are consistent with the eccentric loading described . . . in my general report associated with Zimmer High Flex implants." (*Id.*)

Dr. Fetto opines that higher flexion "puts excessive stress on the component-cement interface and can lead to early failure." (*Id.* at 5.) Dr. Fetto concludes that the design of the implant, combined with high-flexion activities, caused the device to become "debonded from the cement" used in the interface. (*Id.*) Dr. Fetto does not refer to any literature or give any explanation for why the implant design, and asymmetric loading generally, causes debonding, and in turn, loosening. He does assert that aseptic failure of the tibial component is recognized in the medical literature—the court presumes that he is referring to literature recognizing aseptic failure of the NexGen Flex's tibial component—but he does not cite to specific studies. (*Id.*) In sum, Dr. Fetto attributes Joas's component loosening to asymmetric loading: "Joas'[s] tibial implant loosened because of the asymmetric loading related to its design." (*Id.*)

[7] *See Batty* Opinion, 2015 WL 3669933, at *9 n.11 ("The bottom of each femur has two "condyles"—or rounded prominences—that enable the femur to "articulate," or move easily, along the top of the tibia as the knee flexes.").

IV. Zimmer's Warnings

Along with each NexGen Flex device, Zimmer includes a "package insert" containing instructions about implanting the device and warnings about the product's risks, including the risk of component loosening. Plaintiffs insist that Zimmer's warnings are inadequate. At his deposition, Joas testified that he remembered reading written materials that were "probably from Zimmer," assuring him he "would get back to [his] active style, that [the implant] is a good knee." (Joas Dep. 168:15–169:8.) Plaintiffs note that Zimmer's marketing materials did not mention that high-flexion activities may cause early failure of the NexGen Flex device. But as Zimmer points out, Dr. Larson, Joas's implanting surgeon, testified at his deposition that he, himself, never reviewed the relevant the package inserts prior to performing Joas's TKR surgery. (Dep. of Bryan Larson, Ex. D to Def.'s Reply in Supp. of Mot. for Summ. J. [129-5] (hereinafter "Larson Dep."), at 83:24–84:24.)

Plaintiffs also assert that Zimmer's surgical technique instructions were deficient. In particular, they rely on the testimony of one of Zimmer's experts, Dr. John Dearborn, who believes that the one bag of cement that Dr. Larson used to affix Joas's implant to his bones was inadequate. (Dep. of John Dearborn, Ex. 6 to Pls.' Mem. in Opp'n. to Def.'s Mot. for Summ. J. [114-6] (hereinafter "Dearborn Dep."), at 50:1–5.) According to Dr. Dearborn, cement should be applied across the entire tibial plateau at a consistent and continuous level of thickness. (*Id.* at 106:25–107:6.) Had Dr. Larson properly cemented Joas's device, using at least two bags of cement, Dr. Dearborn believes that Joas's knee implant would not have failed as early as it did. (*Id.* at 82:24–83:2.) Zimmer's Surgical Technique Guide for the NexGen Flex device does address cementing; it directs that "[i]f bone cement is being used, [surgeons should] apply cement to the underside of the tibial plate, around the keel, on the resected tibial surface, and in the tibial IM canal." (Zimmer Surgical Technique Guide, Ex. 17 to Pls.' Resp. to Zimmer's Stmt. of Undisputed Material Facts [115-17], at 11.) Plaintiffs point out that the guide does not specify the number of cement bags that a surgeon should use. Dr. Dearborn's expert

report, however, states expressly that "[t]he basic surgical technique for implanting the [NexGen Flex] is well-documented in Zimmer's Surgical Technique Guide, but surgeons are primarily guided in their technique by the basic medical training they received during residency and/or fellowship training." (Report of Dr. John Dearborn, Ex. C to Def.'s Reply Mem. in Supp. of Mot. for Summ. J. [129-3] (hereinafter "Dearborn Rep."), 18.) Dr. Larson testified that he reviewed "parts of" the surgical technique guide back in the early 2000s, but confirmed that he learned his surgical technique—including the technique for cementing the components—"from [his] residency and [his] fellowship training." (Larson Dep. 85:13–86:6.)

DISCUSSION

I. Zimmer's Motion to Exclude Dr. Fetto's Testimony

A. *Daubert* Standards

Rule 702 of the Federal Rules of Evidence, which governs the admissibility of expert testimony, states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> > (b) the testimony is based on sufficient facts or data;
> > (c) the testimony is the product of reliable principles and methods; and
> > (d) the expert has reliably applied the principles and methods to the facts of the case.

In *Daubert*, the Supreme Court held that the Federal Rules of Evidence requires the trial judge to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 597. The court "must determine whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will 'assist the trier of fact to understand the evidence or to determine a fact in issue.'" *Myers*, 629 F.3d at 644 (quoting *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir.2007)).

In assessing reliability, the court may look at factors such as "(1) whether the scientific theory or technique can be (and has been) tested; (2) whether the theory or technique has been

subjected to peer review and publication; (3) whether a particular technique has a known potential rate of error; and (4) whether the theory or technique is generally accepted in the relevant scientific community." *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013) (citing *Daubert*, 509 U.S. at 593–94); *see also Stollings v. Ryobi Technologies, Inc.*, 725 F.3d 753, 766 (7th Cir. 2013) ("Rule 702's reliability elements require the district judge to determine only that the expert is providing testimony that is based on a correct application of a reliable methodology and that the expert considered sufficient data to employ the methodology."). These factors, however, do not apply "to all experts or in every case." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). In its gatekeeping role, the court has discretion over how to assess the reliability of the expert testimony. *Id.* at 152.

Even if the methodology is reliable, the "expert still must faithfully apply the method to the facts at hand." *Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 772 (7th Cir. 2014). The expert must "rely on 'facts or data,' as opposed to subjective impressions." *Id.* Thus, "[t]he expert must explain the methodologies and principles supporting the opinion." *Minix v. Canarecci*, 597 F.3d 824, 835 (7th Cir. 2010). Conclusions alone, without the explanations or support for those conclusions, are inadmissible. *Wendler & Ezra, P.C. v. Am. Int'l Grp., Inc.*, 521 F.3d 790, 791 (7th Cir. 2008) ("'An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process.'") (quoting *Mid-State Fertilizer Co. v. Exchange Nat'l Bank*, 877 F.2d 1333, 1339 (7th Cir.1989)).

Although the court must assess whether the expert's methodology is reliable, "Rule 702's requirement that the district judge determine that the expert used reliable methods does not ordinarily extend to the reliability of the conclusions those methods produce—that is, whether the conclusions are unimpeachable." *Stollings*, 725 F.3d at 765–66 (citing *Daubert*, 509 U.S. at 595). So long as the expert's testimony is "based on a valid and properly applied methodology," it is admissible even if the expert reaches "a conclusion that is subject to doubt." *Stollings*, 725 F.3d at 766. "[T]he accuracy of the actual evidence is to be tested before the jury

with the familiar tools of 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 805 (7th Cir. 2012) (quoting *Daubert*, 509 U.S. at 596).

Dr. Fetto performed a differential etiology to reach his opinions in this case. "[I]n a differential etiology, the doctor rules in all the potential causes of a patient's ailment and then by systematically ruling out causes that would not apply to the patient, the physician arrives at what is the likely cause of the ailment." *Myers*, 629 F.3d at 644. An effective differential etiology "must be based on scientifically valid decisions as to which potential causes should be 'ruled in' and 'ruled out.'" *Ervin*, 492 F.3d at 904. "The question of whether it is reliable under *Daubert* is made on a case-by-case basis, focused on which potential causes should be 'ruled in' and which should be 'ruled out.'" *Myers*, 629 F.3d at 644 (citing *Ervin*, 492 F.3d at 904). "[A]n expert [applying a differential etiology] must do more than just state that she is applying a respected methodology; she must follow through with it." *Brown*, 765 F.3d at 773. "[T]he district court has discretion to consider '[w]hether the expert has adequately accounted for obvious alternative explanations.'" *Id.* (quoting *Schultz*, 721 F.3d at 434) (second alteration in original). Though an expert is not required to "exclude all alternatives with certainty," *Brown*, 765 F.3d at 773 (citing *Gayton v. McCoy*, 593 F.3d 610, 619 (7th Cir.2010)), an opinion based upon a differential etiology may be excluded when "there is simply too great an analytical gap between the data and opinion proffered such that the opinion amounts to nothing more than the *ipse dixit* of the expert . . . ." *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 837 (7th Cir. 2015) (internal citations omitted).

The court applies these standards in assessing the reliability of Dr. Fetto's differential etiology.

B. Dr. Fetto's Report

Dr. Fetto's credentials are described at length in the court's opinion in *Batty*. *Batty* Opinion, 2015 WL 3669933, at *19–20. Zimmer does not challenge Dr. Fetto's qualifications nor the relevance of his testimony. Zimmer instead takes aim at the reliability of his methods and application of those methods. (Zimmer's Reply in Supp. of its First Daubert Mot. to Exclude Test. of Dr. Joseph Fetto [126] (hereinafter "Def.'s Fetto Reply"), at 1). As explained below, the court concludes that Dr. Fetto's methods are not adequately reliable for two reasons. First, Dr. Fetto does not explain how he reaches many of his conclusions. Most prominently, he fails to offer any new support for a number of opinions that the court found to be inadequately explained in *Batty*. Second, Dr. Fetto uses inconsistent bases for ruling causes in and out of his differential etiology, such that his etiology is not systematic and the court cannot conclude that it is reliable.

1. Bases for Dr. Fetto's Conclusions

Dr. Fetto repeats his general design defect conclusions, held inadmissible in *Batty*, but offers no additional support or explanation here. First, Dr. Fetto opines that the implant interface "is extraordinarily vulnerable to loads that are asymmetric causing a tensile force . . . to be applied[.] [When combined with high flexion,] this puts excessive stress on the component-cement interface and can lead to early failure." (Fetto Rep. at 4–5.) In *Batty*, however, the court excluded his opinion that high flexion causes greater forces pulling the bone and component apart from each other. *Batty* Opinion, 2015 WL 3669933, at* 23. Despite this rejection, Dr. Fetto has not yet explained why his opinion on this issue—that the design causes a tensile force that strains the interface—is reliable.

Instead, Dr. Fetto simply states that "[i]t was recognized in Zimmer's design team literature[,] internal documentation[,] outside documentation and . . . orthopedic literature that this asymmetric loading of high-flexion devices can cause aseptic failure[.]" (Fetto Rep. at 5.) Dr. Fetto concludes that "Joas'[s] tibial implant loosened because of the asymmetric loading

related to its design." (Fetto Rep. at 5.) Ultimately, he declares summarily that the "Zimmer NexGen Legacy LPS-Flex device . . . has a propensity for aseptic failure due to high flexion activities." (Fetto Rep. at 6.) "An expert who supplies nothing but a bottom line supplies nothing of value to the judicial process." *Wendler & Ezra*, 521 F.3d at 791. In neither *Batty* nor this case has Dr. Fetto given the court sufficient basis to conclude that his opinion is reliable.

Second, Dr. Fetto provides almost no explanation of how the sources he reviewed support his conclusions. He claims in his deposition that examining Joas's explant helped him conclude that there was no excessive wear of the polyethylene (Fetto Dep. 215:21–216:2), but he does not describe what he observed when examining the components, or how they differ from components that do show excessive wear that might cause loosening. Dr. Fetto also claims that he reviewed the medical records of "dozens of other individuals" that support his conclusions, but has not described what he saw in those records. Plaintiffs argue that they provided Zimmer with Dr. Fetto's opinions regarding the medical reports of these other individuals (Pls.' Memo. in Opp'n to Zimmer's Mot. to Exclude Test. of Dr. Joseph Fetto [92] (hereinafter "Pls.' Fetto Mem."), at 11), but even if that is the case, Plaintiffs have not directed the court to any of this information, making it difficult for the court to assess whether Dr. Fetto's use of these other medical records to support his conclusions is reliable.

Zimmer did not move to exclude Dr. Fetto's plaintiff-specific opinions in *Batty*. (*See* Def.'s Mem. in Supp. of Second *Daubert* Mot., Case No. 11 C 5468 [1301] (hereinafter "Def.'s *Batty* Fetto Mem."), at 1 ("Dr. Fetto is an experienced surgeon who is qualified to give his case-specific medical opinion about Plaintiff Kathy Batty.").) Dr. Fetto's case-specific opinion in that case was supported in large part by radiographic evidence consistent with mechanical failure of her implant's fixation. (*See* Report of Dr. Joseph Fetto, re: Kathy Batty (July 11, 2014), Ex. L to Ronca Decl., Case No. 11 C 5468 [1464-12], at 3 (describing progressive radiolucency about tibial and femoral components; good fixation, cement, and alignment; as well as lucencies around tibial cement mantle, tibial subsidence, and evidence of resorption on anterior and

posterior of "distal femoral bone-prosthesis interface").) Zimmer points out that, by contrast, Dr. Fetto fails to provide such radiographic support for the opinions in his *Joas* report or to even offer any analysis of Joas's x-rays. (Def.'s Fetto Mem. at 20.) Plaintiffs argue that it is "preposterous to suggest" that Dr. Fetto did not look at the records he listed in the appendix to his report, specifically Joas's x-rays. (Pls.' Fetto at Mem. 5.) Indeed, the court presumes that Dr. Fetto did review x-rays and other records. Disappointingly, however, Dr. Fetto does not explain what he saw when he reviewed those records or how what he saw supported his conclusions. The only description of a medical record in his report is his quotation from Dr. Decesare's description of Joas's x-ray. (Fetto Rep. at 2.) Plaintiffs claim that Dr. Fetto's observations were consistent with Dr. Cameron's conclusions, so describing them would have been redundant. (Pls.' Fetto Mem. at 6.) But Plaintiffs cannot simultaneously rely on Dr. Fetto's observations as support for his conclusions and also decline to describe those observations; redundant or not, a review of those observations could enable the court to assess whether Dr. Fetto reliably used acceptable methods and principles. Plaintiffs make much of the fact that Zimmer did not show Dr. Fetto any x-rays in his deposition (*id.* at 7), and that he answered questions about the x-rays when asked (*id.* at 6), but it is incumbent on Dr. Fetto to explain how Joas's x-rays informed his opinions, if they indeed served as a basis for those opinions.

Dr. Fetto's treatment of scientific literature is similarly lacking. Dr. Fetto lists dozens of articles in the appendix to his *Joas* report that he apparently reviewed, and, as Plaintiffs point out, Dr. Fetto conducted a literature review in his general report. (Pls.' Fetto Mem. at 21.) But Dr. Fetto does not describe how any of the articles support his conclusions. Indeed, as Zimmer points out, several articles were released after Dr. Fetto's general report, but Dr. Fetto provides no discussion in his *Joas* report about any of these new articles, making it difficult to assess their relevance. (Def.'s Fetto Mem. at 10 n.18.) As described above, Dr. Fetto's opinions here are the same as those in the general report, which the court excluded precisely because Dr. Fetto did not reliably support his conclusions. Plaintiffs note that in *Batty*, the court found that

"Dr. Fetto cites several studies showing a higher revision rate for Zimmer high flex knees than for non-flex knees." (Pls.' Fetto Mem. at 21–22.) Disingenuously, Plaintiffs leave out the court's conclusion in that paragraph: "Dr. Fetto has not, however, sufficiently explained why he sees a link between the higher revision rates and the evidence of posterior loading." *Batty* Opinion, 2015 WL 3669933, at *22. Dr. Fetto's listing of articles, without any discussion, provides no more than the insufficient explanation in Dr. Fetto's general report.

Expert testimony necessarily requires judgment on the part of experts to reach their opinions. This judgment must be reasoned, however, and must be presented in a way that a court can determine is based on reliable methods that are reliably applied. Plaintiffs emphasize Dr. Fetto's years of experience and the extent of the sources that he reviewed (Pls.' Fetto Mem. at 15–16, 18), but without an explanation for how those sources support his conclusions, the court has no way to verify that Dr. Fetto uses those sources in a reliable way.

2. Differential Etiology

A differential etiology must *systematically* rule potential causes in and out. *Myers*, 629 F.3d at 644. A potential expert must therefore explain why each cause was ruled in, and why any are ruled out. *See Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 705 (7th Cir. 2015) (upholding the exclusion of expert testimony when "the record is silent on whether Dr. Haacke considered other possible causes of Higgins's ailments and, if so, how and why she ruled them out. That is problematic, because Higgins told the district court that Dr. Haacke had assessed the cause of his ailments by employing 'differential diagnosis.'"). Because Dr. Fetto does not follow identifiable standards for including or omitting causes potential causes for Joas's knee failure, his methods do not appear to meet that test.

a. Causes Ruled In

First, Dr. Fetto has identified no consistent standards for ruling causes *in* to his differential etiology. A differential etiology requires that an expert rule in all "reasonable" potential causes before systematically excluding them. *Ervin*, 492 F.3d at 903. Plaintiffs are

correct that an expert need not consider *every* possible cause. (Pls.' Fetto Mem. at 16.) An expert should, however, have a discernable basis for determining which potential causes are reasonable. Dr. Fetto's apparent criteria for ruling in reasonable potential causes vary considerably. Of particular concern are (1) his decision not to rule in osteolysis, a cause of loosening which can result from cement debris and polyethylene wear, (2) his decision not to rule in a cement defect, and (3) his decision to rule in a design defect.

i. Osteolysis

Dr. Fetto admits that osteolysis[8] is a possible cause of tibial component loosening. (Fetto Dep. 87:19–88:9.) Dr. Fetto agrees, further, that osteolysis can be caused by both cement debris and polyethylene wear. (Fetto Dep. 87:19–88:9.) Zimmer contends that Dr. Fetto should have ruled in both cement debris and polyethylene wear as potential causes of Joas's implant failure, because both can cause osteolysis. (Def.'s Fetto Mem. at 15–16.)

In evaluating this concern, the court notes, as an initial matter, that it is not clear from Dr. Fetto's report whether he ruled cement debris in and then ruled it out, or simply did not consider it at all. The report does refer to "microscopic particulate debris which causes an immunologic reaction in the bone" in reference to polyethylene wear, but not cement debris. Dr. Fetto's list of "reasonable possibilities," refers to both "problems with the cement" and "particulate debris," but, again, it is unclear whether the reference to debris refers only to polyethylene wear, or includes other debris that can cause osteolysis, as well. (Fetto Rep. 3.) In the section of the report where Dr. Fetto rules out causes, such as infection and surgical technique, he mentions neither "problems with the cement" nor "particulate debris," and he opines later in his report that that there was "excellent bond to the cement." (*Id.* at 3–4.) Dr. Fetto explains in his deposition that "problems with the cement" means "[t]hat the bond between the cement and the device breaks down," by which he could mean cement fragmentation. (Fetto Dep. 259:10–13.) Dr. Fetto also opines, however, that any cement debris would be the result, not the cause, of

[8] "Osteolysis" refers to degradation of bone, which can occur in response to foreign body debris. Dorland's Medical Dictionary; (Def.'s Fetto Mem. at 8 n.14.)

component loosening, further indicating that he did not "rule in" osteolysis from cement debris as a potential cause. (*Id.* at 211:21–212:17.) Finally, Dr. Fetto states that he does *not* reach any opinion about whether Joas developed osteolysis. (*Id.* at 208:20–24.) The court concludes that Dr. Fetto did not rule in osteolysis from cement debris as a potential cause of Joas's component loosening.

The failure to include osteolysis resulting from cement debris as a cause is problematic because Dr. Fetto admits that osteolysis from cement debris is a potential cause of component loosening generally (Fetto Dep. 87:19–88:9), and offers no explanation for his failure to address it as a potential cause for failure of Joas's implant. Plaintiffs emphasize that Dr. Fetto's decisions to rule out possible causes were based upon careful reviews of Joas's medical records and radiographic images (Pls.' Fetto Mem. at 4), but Plaintiffs do not explain what standard Dr. Fetto used to create his list of reasonable causes in the first place or why that standard would leave cement debris off the list. Most troublingly, Plaintiffs assert that cement debris cannot be a cause of the loosening because the loosening was caused by asymmetric loading of the device. (*Id.* at 7.) Not only does Dr. Fetto himself fail to support this conclusion in his report, but this argument *assumes the result of the differential etiology*. Dr. Fetto's decision to exclude osteolysis resulting from cement debris casts doubt on the systematic nature of his analysis overall.

Plaintiffs brush this concern aside, asserting that Dr. Fetto had good reason to exclude osteolysis in general as a cause of Joas's implant failure. As mentioned above, Dr. Fetto does allude to osteolysis—"immunologic reaction in the bone"—once in his report and only as a potential response to particulate debris caused by polyethylene wear. (Fetto Rep. at 2.) He dismisses the possibility of osteolysis because Dr. Cameron testified that he did not observe a dramatic amount of polyethylene wear debris on Joas' explanted device,[9] but that observation is

[9] As with osteolysis caused by cement debris, it is unclear whether Dr. Fetto rules in, and then rules out, osteolysis caused by polyethylene wear, or simply declines to rule it in at all. The parties also dispute whether it was appropriate to exclude polyethylene wear as a

not a basis for dismissing the possibility of osteolysis caused by cement debris. Dr. Fetto only dismissed osteolysis as a cause in general when pressed about the point during his deposition. (Fetto Dep. 212:24–213:11.) Confronted with the fact that Joas's tibia did develop osteolysis in one small area, Dr. Fetto opined summarily that there was "no significant osteolysis that we formally would associate with osteolytic reactions." (*Id.* at 213:3–6.) Dr. Fetto's exclusion of osteolysis resulting from cement debris could have been justified, or at least excusable, if he provided a good reason to exclude osteolysis in general as a cause of implant failure. Apart from a summary response to a question at his deposition, however, Dr. Fetto provides no analysis to justify such a general exclusion.

ii. Cement Defect

Zimmer contends that Dr. Fetto should have considered a defect in the cement itself as a cause of Joas's knee failure. (Def.'s Fetto Mem. at 15.) Plaintiffs apparently agree that Dr. Fetto does not rule in such a defect at all, characterizing it as a "far-fetched, baseless alternative cause." (Pls.' Fetto Mem. at 16.) Dr. Fetto acknowledges that "theoretically, a defect in the quality of the cement is a possibility" (Fetto Dep. 343:21–23), but explains that he did not rule it in as a potential cause because he had no information about a recall of the type of cement used and no other reason to suspect a defect in the cement. (Fetto Dep. 343:12–347:15.) Dr. Fetto also admits that he did not do any research to determine whether he should include a cement defect as a reasonable possible cause. (Fetto Dep. 344:19–347:15.)

The problem here is not necessarily that Dr. Fetto did not consider a cement defect as a reasonable cause of Joas's implant failure; the court has no basis for knowing whether a cement defect is a reasonably possible cause or not. But Dr. Fetto's failure to consider such a defect illustrates an inconsistent standard: He excludes a cement defect as a possible cause because he has no personal memory of any recall of the cement product Dr. Larson used, but

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potential cause of osteolysis merely because Dr. Cameron found that the explanted component lacked significant polyethylene wear debris. That dispute, however, appears to be the kind that could be the subject of cross-examination, and the court declines to resolve it.

he ignores the absence of a product recall in considering the possibility of a design defect in Joas's knee implant. Dr. Fetto looked for studies addressing tibial component loosening (*see* Fetto Dep. 177:8–178:5), but performed no such research for cement defects. (Fetto Dep. 344:19–348:9.) In short, Dr. Fetto appears to use different standards for a cement defect and a defective knee implant to determine which potential causes are reasonable and should be ruled in. This inconsistency further undermines the court's confidence in the reliability of Dr. Fetto's method.

iii. Design Defect

Dr. Fetto's decision to rule in mechanical failure from a design defect is also problematic in its own right. As in *Batty*, Dr. Fetto has not presented a sufficient basis to conclude that a design defect in Joas's knee implant was a potential cause of the implant's loosening. In a differential etiology, an expert must have a sufficient, reliable justification for ruling in each potential cause into the etiology in the first place. *Cf. Wood*, 807 F.3d at 838 ("[The differential etiology] nevertheless contains a fatal flaw: ruling in vinyl chloride as a cause in the first place. Without the benefit of analogous studies and an acceptable method of extrapolation, Dr. Byers, like the other experts, is forced to take a leap of faith in pointing to vinyl chloride as having the *capacity* to cause the injuries (and risk of injury) to C.W. and E.W.") (emphasis in original).

Dr. Fetto supplies no such justification for ruling in a design defect as a possible cause. First, in his report, Dr. Fetto does not explain why he concludes that a design defect caused Joas's loosening other than to repeat the opinions in *Batty*—opinions this court excluded precisely because they had insufficient support. Second, at his deposition, Dr. Fetto offered several studies—*Bini*, *Namba*, and the Australian Registry Table K8—that he claims support this conclusion (Fetto Dep. 166:1–168:19), but makes no mention of these studies in his report. Zimmer contends that these studies do not support his conclusions: the Australian Registry Table K8 refers to different kinds of components; *Bini* does not attribute any problems to the Flex component design, and found tibial loosening to be uncommon; and *Namba* does not

discuss tibial loosening, and concerns a different tibial liner.[10] (Def.'s Fetto Mem. at 24–26.) Plaintiffs have made no response to this, and as noted, Dr. Fetto himself offers no explanation for how these studies support his opinion.

In sum, Dr. Fetto inconsistently determines which potential causes are reasonable and should be ruled in. He does not articulate what standard he used: Causes that are known in the literature? Causes Dr. Fetto (or Dr. Cameron) personally observed? Causes that Zimmer warned about? All of these are implicated in the causes that Dr. Fetto rules in, yet he employs none of them *consistently*. Because the entire differential etiology rests on his systematically ruling causes in and out, this inconsistency undermines the reliability of the differential etiology itself.

b. Causes Ruled Out

Dr. Fetto's decisions to rule *out* causes are problematic, as well. Like the decision to rule in causes as reasonably possible, the decision to rule out causes must be systematic. *Myers*, 629 F.3d at 644. Dr. Fetto rules out (1) polyethylene wear debris and resulting osteolysis, (2) surgical technique, and (3) Joas's arthritis medications, yet he does so for different and inconsistent reasons.

i. Polyethylene Wear Debris and Osteolysis

In ruling out polyethylene wear debris and resulting osteolysis, Dr. Fetto relies heavily on Dr. Cameron's testimony—it is the only justification for ruling it out described in his report. (Fetto Rep. at 2–3.) Relying on the testimony of another doctor is not always a sufficient basis for ruling out a potential cause. In *Wood*, the Court of Appeals upheld the exclusion of a differential etiology that ruled out causes because the expert concluded "these causes would

[10] Dr. Fetto does not cite to the *Namba* study, but this appears to be the same study he referred to in his opinions in *Batty*—where he also did not provide a citation. *Batty* Opinion, 2015 WL 3669933, at *22 & n.26; (Def.'s Fetto Mem. at 24 n.34). In *Batty*, the court noted that even though he cited this publication, Dr. Fetto did not "sufficiently explain[] why he sees a link between the higher revision rates and the evidence of posterior loading." *Batty* Opinion, 2015 WL 3669933, at *22. Dr. Fetto makes no effort to cure this deficiency in his *Joas* report.

have been detected by [the appellants'] doctors and treated accordingly." *Wood*, 807 F.3d at 837 (alteration in original) (internal quotation marks omitted). That is arguably what happened here. The only reason that Dr. Fetto gives in his report for excluding polyethylene wear is that "Dr. Cameron testified that there was not a dramatic amount of wear debris." (Fetto Rep. at 2.) Dr. Fetto's opinion appears to be an improvement on what happened in *Wood*. Dr. Fetto does not simply speculate about what Dr. Cameron "would have found"; he notes Dr. Cameron's specific testimony that he did *not* find significant wear, and suggests that Dr. Fetto's examination of the explanted device did not give him reason to question that finding. Yet Dr. Fetto, who had at least as good, and probably better, opportunity to examine the explanted knee, does not describe what he looked for when examining the component, what he observed, what standard he employed to determine whether any wear was "excessive" or "dramatic," or why Dr. Cameron's observations during knee replacement surgery should be given primary weight. Even so, Dr. Fetto's conclusion might be admitted, subject to cross examination, *Daubert*, 509 U.S. at 596, but his conclusion regarding polyethylene wear is only relevant in this case as part of his larger differential etiology, which is itself riddled with other methodological defects.

ii. Surgical Technique

Plaintiffs and Zimmer dispute what the evidence shows about Dr. Larson's surgical technique—specifically whether Dr. Larson applied cement to every surface of the tibial component. (Def.'s Fetto Mem. at 17; Pls.' Fetto Mem. at 17.) In such a situation, the court would expect Dr. Fetto to express an opinion concerning Dr. Larson's surgical technique and the basis for that opinion, but Dr. Fetto has not done so. Dr. Fetto simply states that he did not find "any evidence of poor surgical technique or improper surgical technique[.]" (Fetto Rep. at 3–4.) The court acknowledges that Dr. Fetto need not prove a negative when ruling out causes: if he does not see evidence of a cause in the medical records, it is proper to say so. But Dr. Fetto does not explain what he looked for or what he would characterize as poor or improper

surgical technique; in other words, what kind of surgical technique would cause loosening, and how is that different from what Dr. Larson did? Had Dr. Fetto provided this reasoning, the court could examine it, and it could be a basis for cross examination at trial. Without it, however, the court cannot determine whether Dr. Fetto's opinion of the surgical technique is reliable. Dr. Fetto himself declares that surgical error is "the most common reason for failure of devices today" (Fetto Dep. 258:20–259:9), and one of Zimmer's experts has specifically opined that Joas's implant would not have failed as early as it did had Dr. Larson adequately cemented the device. (Dearborn Dep. 82:24–83:2.) But Dr. Fetto fails to address this concern in his report.

Even more puzzling, however, is that Plaintiffs themselves now assert that improper cementing technique caused Joas's implant to loosen. They state that it is an undisputed material fact that "[b]ecause Mr. Joas' knee replacement was cemented with only one package of cement, it did not supply enough material to cover all of the bony surfaces adequately and caused the implant to loosen." (Pls.' Rule 56.1 Stmt. of Add'l Undisputed Mat. Facts [115] ¶ 6.) Plaintiffs rely on this statement in support of their alternative failure-to-warn theory that Zimmer failed to provide surgeons with adequate instructions concerning the amount of cement to use. Parties are, of course, permitted to make arguments in the alternative. The problem with Plaintiffs' doing so in this instance is that Dr. Fetto's causation opinion is based on ruling out alternative causes that lack evidentiary support. By representing to the court that there is adequate support for the proposition that improper cementing caused Joas's implant to loosen, Plaintiffs undermine the reliability of Dr. Fetto's analysis, which rests on Dr. Fetto's summary conclusion that surgical technique was not a cause of the implant's loosening.

iii. Medications

Dr. Fetto similarly rules out bone damage from Joas's arthritis medications,[11] stating only that he "considered" them, but not explaining how he reaches his conclusion. (Fetto Rep. at 6.)

[11] In his report's appendix, Dr. Fetto lists a number of drug product labels, presumably for drugs Joas was taking or had taken, that he reviewed in forming his opinion. (*See* Fetto Rep. at 7–8.) At Dr. Fetto's deposition, Zimmer's counsel focused on two of the

Dr. Fetto does not explain how any of the sources he reviewed militate against the conclusion that medications could have contributed to the implant loosening. Yet Dr. Fetto acknowledges that bone damage is a risk of at least one of Joas's medications. (Fetto Dep.128:18–133:6.) Perhaps Dr. Fetto relies on Dr. Larson's and Dr. Cameron's observations of Joas's bone quality (*Id.* at 315:2–16), to conclude that Joas's medications did not cause the component loosening. But he does not say so in his report, and the court is unwilling to speculate about what Dr. Fetto's decision-making process was, what basis he has to overcome the known risks of Joas's medications, or why that basis is sufficient to overcome those risks.

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Zimmer contests several of Dr. Fetto's other decisions to rule in or out many other potential causes, including what Zimmer identifies as the most likely cause: the combination of Joas's weight, flexion, and activity levels. Joas's BMI was 31, which qualifies as clinically obese, and he worked a physically demanding job that required repeated lifting and carrying heavy loads. If Dr. Fetto had described his basis for ruling in and out possible causes, Zimmer would have been able to cross examine Dr. Fetto on that reasoning at trial. The court does not, however, determine whether Dr. Fetto has sufficiently supported his opinions other than the ones described here. Regarding the causes described above, Dr. Fetto does not even explain to the court what his reasoning is, how the sources he reviewed inform his conclusion, or why he applies the methods that he does. These problems render the etiology unreliable even

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drugs in particular: prednisone (an anti-inflammatory corticosteroid) and methotrexate (an anti-metabolite medication). Counsel for Zimmer says that, at his deposition, Dr. Fetto produced the warnings and instructions he reviewed, and that they came from the websites of the drugs' manufacturers. (Tr. of Oct. 6, 2016 Hr'g [160], 18:20–22.) Both prescription drugs are indicated for treatment of rheumatoid arthritis, among other conditions. The court's review of the drug's warning labels reveals that decreased bone density, through decreased bone formation and increased bone resorption, is indeed a known risk of corticosteroids like prednisone. Highlights of Prescribing Information for RAYOS (prednisone), http://www.rayosrx.com/pi/RAYOS-Prescribing-Information.pdf (last visited Oct. 19, 2016), at 1, 6. It is not as clear from the product label that methotrexate can lead to decreased bone quality of the kind relevant here. It does appear that methotrexate may increase bone marrow suppression, but Zimmer does not explain how that potential side effect would lead to an implant's loosening. Highlights of Prescribing Information for RASUVO (methotrexate), http://cdn.rasuvo.com/assets/pdf/Prescribing-Information-current.pdf (last visited Oct. 19, 2016).

without addressing Zimmer's other arguments. *See Brown*, 765 F.3d at 774 (failure to meaningfully consider and rule out potential alternative causes in conducting differential etiology is "fatal to [the expert's] testimony"); *Ervin v. Johnson & Johnson, Inc.*, No. 2:04CV0205-JDT-WGH, 2006 WL 1529582, at *6 (S.D. Ind. May 30, 2006) (flaw in ruling in a cause and flaw in ruling out another cause were critical and render differential diagnosis unreliable), *aff'd,* 492 F.3d 901 (7th Cir. 2007) (agreeing that "critical flaws" rendered expert opinion unreliable).

II. Zimmer's Motion for Summary Judgment

The court will grant a motion for summary judgment if the moving party shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). The court construes the evidence in the light most favorable to Plaintiffs, the non-moving parties, and draws all reasonable inferences in their favor. *Carson v. ALL Erection & Crane Rental Corp.*, 811 F.3d 993, 995 (7th Cir. 2016). Plaintiffs are not entitled, however, to inferences relying on "mere speculation or conjecture." *Id.* at 997. Rather, to survive summary judgment, Plaintiffs "must present evidence sufficient to establish a triable issue of fact on all essential elements of [their] case." *Lewis v. CITGO Petrol. Corp.*, 561 F.3d 698, 702 (7th Cir. 2009). It also follows, therefore, that if an element of a claim requires expert testimony and that expert testimony is inadmissible under *Daubert*, the court must grant summary judgment on that claim. *See Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 905 (7th Cir. 2007). The parties agree that Plaintiffs' claims are governed by the substantive law of Wisconsin, which is where Joas's surgery and alleged injury occurred. As mentioned above, Plaintiffs fail to respond to Zimmer's motion for summary judgment regarding the following claims: strict liability manufacturing defect, negligent misrepresentation, breach of express warranty, breach of implied warranty, violation of Wisconsin consumer protection law, unjust enrichment, and fraudulent concealment. The court grants summary judgment on those counts. *See* FED. R. CIV. P. 56(c).

The court's concerns about Dr. Fetto's proposed testimony, described above, could themselves require the court to grant summary judgment on Plaintiffs' remaining claims for design defect, failure to warn, negligent design, and punitive damages. Apart from Dr. Fetto, Plaintiffs have not designated an expert witness who will testify that some defect in Joas's knee implant was the cause of his injury. Causation is an essential element of each of Plaintiffs' remaining claims. *See* Wis. Stat. 895.047(1)(e) (requiring plaintiff to establish that a product's "defective condition was a cause of the claimant's damages" for strict products liability claim, whether based on manufacturing defect, design defect, or failure to warn or instruct); *Rockweit by Donohue v. Senecal*, 197 Wis. 2d 409, 418, 541 N.W.2d 742, 747 (1995) (requiring "causal connection between the conduct and the injury" for plaintiff to maintain cause of action for negligence); *Kehl v. Econ. Fire & Cas. Co.*, 147 Wis. 2d 531, 533, 433 N.W.2d 279, 280 (Ct. App. 1988) (punitive damages cannot be awarded for conduct that "did not cause or contribute to the plaintiff's loss"). The question of what caused the tibial component of Joas's implant to loosen is a matter outside the common knowledge and everyday experience of a lay juror, and thus Plaintiffs cannot establish causation without the support of expert testimony. *See Bochek v. W. Bend Mut. Ins. Co.*, 2013 WI App 94, ¶ 25, 30, 349 Wis. 2d 527 (Ct. App. 2013) (expert testimony required to establish cause of plaintiff's knee pain).

Plaintiffs contend that Wisconsin law is unusual because of the extent to which it allows lay juries to decide issues without the aid of expert testimony, and they suggest that it would therefore be inappropriate to keep this case from a jury based on the lack of admissible expert testimony supporting causation. Indeed, the Wisconsin Supreme court has cautioned that "[c]losing down a trial is not to be taken lightly, which is why the requirement of expert testimony is an extraordinary one." *State v. Kandutsch*, 2011 WI 78, ¶ 28, 336 Wis. 2d 478, 491, 799 N.W.2d 865, 872. Under Wisconsin law, a court should not require expert testimony without first finding that "the underlying issue is not within the realm of the ordinary experience of mankind." *Id.* (internal quotation marks omitted). But it is not difficult for the court to make that finding in

this case. The "ordinary experience of mankind" provides little insight into what caused Joas's knee implant to loosen prematurely. Had Joas's knee been struck by a baseball bat immediately prior to his component's loosening, had he suffered a ski injury, had he taken a fall—in such circumstances, a causation expert might well be unnecessary. But as the above discussion of Dr. Fetto's proposed testimony makes clear, there are a number of recognized potential reasons why a knee implant might loosen prematurely. Without expert testimony concerning causation and without an obvious external cause for the loosening, a lay jury could only speculate that it was a defect in the implant itself that caused the tibial component to loosen. *See Smith v. Sofamor, S.N.C.*, 21 F. Supp. 2d 918, 921 (W.D. Wis. 1998) (granting summary judgment for lack of expert testimony showing that medical device caused plaintiff's injury and noting that requirement of expert testimony is "consistent with Wisconsin law"). The causation issue in this case, for example, is considerably different from that in *Lindeman v. Mt. Olympus Enterprises, Inc.*, No. 14-CV-435-BBC, 2015 WL 4772925 (W.D. Wis. Aug. 12, 2015), which Plaintiffs relied upon at oral argument. In *Lindeman*, another district court ruled that no expert testimony was needed under Wisconsin law to establish that the plaintiff had injured her back when she experienced immediate pain after being thrown to the back of a roller coaster car that lacked secure restraints. *Id.* at *2. The court concluded that a lay jury could rely on its common experience to determine that the loose restraints were at least *a* cause of the plaintiff's back injury, even if other causes contributed to her injury. *Id.* at *4. In this case, the cause of Joas's injury is not nearly as obvious and cannot be established without admissible medical testimony. *See Smith*, 21 F. Supp. 2d at 921.

The decision to exclude Dr. Fetto's testimony is obviously significant. Even if the court were to permit Dr. Fetto's testimony, however, summary judgment would still be appropriate on all of Plaintiff's remaining claims for the reasons discussed below.

A. Design Defect

Wisconsin's product liability statute, enacted as a part of a "tort reform" initiative in 2011,

provides that "[a] product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). To establish liability for defective design, a plaintiff must also establish that the product's "defective condition rendered the product unreasonably dangerous to persons or property" and that the "defective condition was a cause of the claimant's damages." *Id.* § 895.047(1)(b), (e).

Plaintiffs insist that the "reasonable alternative design" test has not replaced the "consumer expectation" test, under which a product's design is considered unreasonably dangerous, and thus defective, if it is dangerous to an extent beyond that which would be contemplated by the ordinary consumer. *See Green v. Smith & Nephew AHP, Inc.*, 245 Wis. 2d 772, 826, 629 N.W.2d 727, 752 (2001). In support of this assertion, Plaintiffs rely on a comment to a Wisconsin pattern jury instruction, which asks, "Since neither manufacturing defect or a failure to warn/instruct defect implicates product design, how would the reasonable alternative design test apply in these circumstances? Or should the consumer contemplation test be applied to these cases?" (Pls.' Mem. in Opp'n. to Def.'s Mot. for Summ. J. [114], 4 (citing WIS-JI-CIVIL 3260.1).) But the quoted portion of this comment says nothing about the applicability of the consumer expectation test in the design-defect context; it simply asks the reasonable question of how an alternative-design test could apply to claims *other than* those based on defective design.

Plaintiffs also argue that Wisconsin's product liability statute is based on the Restatement (Third) of Torts. As Plaintiffs see things, that means that the consumer expectation test remains relevant even in design defect cases. Plaintiffs note that a comment in the Restatement (Third) provides: "[A]lthough consumer expectations do not constitute an independent standard for judging the defectiveness of product designs, they may substantially influence or even be ultimately determinative on risk-utility balancing in judging whether the

omission of a proposed alternative design renders the product not reasonably safe." Restatement (3d) of Torts: Prod. Liab. § 2 cmt. g (1998). This court is uncertain that this comment in the Restatement (Third) is an accurate statement of the law in Wisconsin. Even if it is, the comment provides only that consumer expectations are a factor to be considered in the ultimate determination of whether the omission of a proposed alternative design renders a product unreasonably safe. *Id.* Other factors to consider include "whether the proposed alternative design could be implemented at reasonable cost, or whether an alternative design would provide greater overall safety." *Id.* Whether or not consumer expectations are an appropriate factor to consider in judging the defectiveness of a product's design, the statutory language makes clear that a plaintiff bringing a design defect claim in Wisconsin must propose a reasonable alternative design, the omission of which renders the product not reasonably safe. Wis. State. § 895.047(1)(a).

1. Lack Of Evidence of a Safer Alternative Design

In addition to Plaintiffs' lack of specific causation evidence, Plaintiffs' design defect claim thus fails under Wisconsin law because they have not offered sufficient evidence of any safer alternative design. Plaintiffs concede that they do not intend to offer opinions about a safer alternative design through Dr. Fetto. (*See* Pls.' Fetto Mem. at 23.) And although Dr. Madigan does opine that the NexGen Flex device likely fails at a greater rate than the NexGen Standard device, he does not offer an opinion that any particular aspect of the Flex device's *design* explains its greater tendency for failure. In addition, Dr. Madigan does not consider whether the utility of the Flex design—its purported ability to allow patients to achieve greater flexion—is outweighed by its alleged tendency for failure. That is, Dr. Madigan does not offer an opinion to establish that the Standard knee is a true "alternative" to the Flex knee, serving the same purpose but with less risk. After all, Plaintiffs' own expert, Dr. Brown, believes that for patients who will engage in high-flexion activities, the NexGen Flex is preferable to the NexGen Standard. *See Batty* Opinion, 2015 WL 33669933, at *17. And Dr. Brown has opined that at

flexion angles below 120 to 130 degrees, there is little reason for concern about the Flex device's safety.[12] (Brown Supp. Rep. at 6–7.) Thus, Plaintiffs have not established that the NexGen Standard constitutes a safer alternative design, and because Dr. Brown and Dr. Madigan offer no opinions about Joas's own case, they offer no opinion that the NexGen standard would provide a safer alternative design for someone like Joas in particular.

The alternative design upon which Plaintiffs appear to rely primarily—and the design they pointed to at oral argument—is the one proposed by Dr. Li and Dr. Rubash. Dr. Brown states that Dr. Li and Dr. Rubash proposed a design modification that was "biomechanically reasonable" and that would have "constituted an alternative" to the Flex design. Significantly, however, Dr. Brown does not offer any opinion—or any analysis in support of an opinion—that the Li/Rubash proposed design would be *safer* than that of the Flex. Indeed, he does not discuss what the proposed design modification was, what made it "biomechanically reasonable," or how it would have reduced any of the risks he identified with the Flex design. None of Plaintiffs' experts, therefore, have identified a design proposal that would constitute a reasonable alternative to the NexGen Flex, the omission of which would render the Flex unreasonably safe. In addition, none of Plaintiffs' experts has offered an opinion that any other knee with a different design would have been safer for Joas. As a result, Plaintiffs cannot prove their claim of a design defect under Wisconsin law.

2. Lack of Evidence that the Flex Design is Unreasonably Dangerous

The lack of admissible expert testimony to support specific causation and the failure to

[12] Although the court allowed the plaintiffs in *Batty* to argue that the Standard knee was a safer alternative design, based on Dr. Brown's opinions, the safer-design theory approved by the court in *Batty* is not available to Plaintiffs in this case. *See Batty* Opinion, 2015 WL3669933, at *38. The court concluded in *Batty* that Dr. Brown could offer an opinion that the two-millimeter bone cut required for implantation of the Flex rendered its design less safe than that of the Standard. But Dr. Brown opined that the two-millimeter bone cut was a problem for the femoral side and did not affect loosening of the tibial component, which is the injury alleged in this case. (*See* Dep. of Thomas Brown in *Batty*, Ex. D to Def.'s Reply Mem. in Supp. of Second *Daubert* Mot. [131-4], 179:10–16.) For that same reason, Dr. Brown's discussion of Dr. Walker's proposed design cannot serve as Plaintiffs' proposed safer alternative in this case. The only feature of that design that Dr. Brown mentions at all is its elimination of the two-millimeter bone-cut requirement.

produce evidence of a safer alternative design are independent bases for the court's grant of summary judgment on Plaintiffs' claim of design defect. But the court also notes concerns about Plaintiffs' ability to establish that the Flex design is unreasonably dangerous with respect to its tendency to cause tibial loosening. As discussed above, Dr. Madigan only opines that the Flex device's rate of failure is likely higher than that of the Standard device. But he does not offer an opinion about the absolute risk of loosening for a patient who receives a Flex device and thus can also offer no opinion about whether such a risk makes the Flex device unreasonably dangerous.[13] In a similar way, Dr. Brown only opines that he believes that the potential for high-flexion activity predisposes the Flex device's tibial component to failure. But he admits that he does not know "whether or not [the] levels of additional toggle moment demand [that he has modeled] would represent an unacceptable risk for fixation interface failure." (Brown Supp. Rep. at 7.) In *Batty*, Dr. Brown made the general statement that the clinical literature suggests that the Flex design's benefit is small and its risk high, meaning that the knee in general has a "bad risk-benefit ratio." (*Batty* Trial Transcript, Ex. 4 to Pls.' Mem. in Opp'n. to Zimmer's Second *Daubert* Mot. [95-4], 1068:24–1069:5.) Dr. Brown has not, however, conducted a risk-benefit analysis with respect to the risk of tibial loosening, the injury at issue in this case. In addition, he suggests that he lacks the expertise to determine whether the Flex design's risks make the product unsafe for implantation, saying he would "leave that judgment to the orthopedic docs . . . . That's a fundamental clinical judgment . . . not a biomechanical judgment." (Brown Dep. 38:7–14.)

Dr. Brown's admirable willingness to recognize the limits of his own analysis lends considerable credibility to his opinions. But in some respects, Dr. Brown's clarifications

[13] It is possible that the Flex device's risk of loosening is higher, even considerably higher, than that of the Standard device, but that the Flex's absolute risk of loosening is still low. If, for example, the odds of failure for one device are .01%, and the odds of failure for a second device are .02%, both devices may well be safe products. The second product is twice as likely to fail; but a reasonable patient or surgeon is not likely to choose one device over the other for that reason.

complicate Plaintiffs' effort to establish that the risk of tibial loosening is unreasonable. Plaintiffs are not required to put forth an expert to say the magic words—that the NexGen Flex's tendency to cause tibial loosening renders the device "unreasonably dangerous." But Plaintiffs must provide sufficient evidence to allow a jury to reach that conclusion without resorting to speculation. Because of the other deficiencies with Plaintiffs' design defect claim in this case, the court need not conclusively determine whether Plaintiffs can establish that the Flex design poses an unreasonable risk of tibial loosening. The court highlights its concern, however, because the same issue may arise in future bellwether cases.

B. Negligent Design

The deficiencies in Plaintiffs' design defect claim similarly doom their claim of negligent design. Without admissible testimony demonstrating that a defect in the Flex design caused Joas's injury, Plaintiffs cannot establish any link between Zimmer's alleged negligent behavior and Joas's injury. And as Plaintiffs themselves point out, "[i]n the negligence context, the reasonableness of a product's design 'turns essentially on whether the seller could have come up with a less dangerous design.'" (Pls.' Mem. in Opp'n. to Def.'s Mot. for Summ J. [114] at 11 (citing *Nationwide Agribusiness Ins. Co. v. Meller Poultry Equip., Inc.*, No. 12-C-1227, 2015 WL 998331, at *3 (E.D. Wis. Mar. 5, 2015)).) As the court discussed above, Plaintiffs have failed to produce evidence of a safer alternative design.

In addition to the problem generated by the exclusion of Dr. Fetto's testimony on causation, Plaintiffs' negligent design claim runs into yet another causation hurdle. In particular, the most plausible of Plaintiffs' allegations of negligent design is that Zimmer failed to conduct adequate testing of the Flex device, but Plaintiffs fail to produce any evidence to establish what such testing would have shown had Zimmer actually conducted it.[14] Plaintiffs suggest that

[14] As discussed below, Plaintiffs also assert that Zimmer was negligent in failing to give adequate warning or instructions. Plaintiffs' other negligence theories—such as Zimmer's rush of the device to market, failure to heed signs that devices were failing at high rates, and failure to investigate complaints and adverse incidents—appear to be variations on a failure-to-test theory.

because it was Zimmer's duty to conduct the required testing and it failed to do so, it is Zimmer—and not Plaintiffs—who carries the burden of demonstrating what such testing would or would not have shown. Plaintiffs offer no support for this burden-shifting approach, and the court sees no reason to adopt it. Plaintiffs are the ones asserting that Zimmer's failure to test constituted negligence and that the lack of testing had some causal relationship with Joas's injury; it is their burden to produce evidence to support such a claim. *See Ehlinger by Ehlinger v. Sipes*, 155 Wis. 2d 1, 12, 454 N.W.2d 754, 758 (1990) ("To establish causation in Wisconsin, the plaintiff bears the burden of proving that the defendant's negligence was a substantial factor in causing the plaintiff's harm.").[15]

Plaintiffs, or their experts, need not conduct such testing themselves. To prove causation on the their negligence claim, however, Plaintiffs must provide some evidence to indicate that appropriate testing would have produced results that would have obligated Zimmer to change the design of its device, thereby preventing Joas's premature loosening. Without such evidence, a jury could only speculate that Zimmer's failure to test bears some causal relationship to the injury Joas suffered. *Cf. Merco Distrib. Corp. v. Commercial Police Alarm Co.*, 84 Wis. 2d 455, 460, 267 N.W.2d 652, 655 (1978) ("A mere possibility of . . . causation is not enough; and when the matter remains one of pure speculation or conjecture or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for defendant."). Plaintiffs' failure to provide such causation evidence provides another reason for the court to grant summary judgment for Zimmer on Plaintiffs' claim of negligent design.

C. Failure to Warn

As the court stated above, without reliable expert testimony concerning the specific cause of Joas's tibial loosening, Joas cannot demonstrate that Zimmer's failure to warn or instruct about some aspect of his knee implant was the cause of his injury. Plaintiffs' failure-to-

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[15] Of course, there is no freestanding claim for "failure to test." Even if a manufacturer had an obligation to test the safety of its product and failed to do so, the company would suffer no liability if the product turned out to be completely safe.

warn claims suffer from additional deficiencies, as well, some of which the court highlights below.

1. Learned Intermediary Doctrine

As an initial matter, the parties dispute whether the so-called "learned intermediary" doctrine applies in Wisconsin. Under that doctrine, the manufacturer or supplier of a prescription drug—or, in this case, a medical device designed for surgical implantation—has no duty to warn the patient receiving the drug or device, as long as the manufacturer or supplier provides adequate warnings to the prescribing physician. As the Illinois Supreme Court has explained, "[t]he underlying rationale of the learned intermediary doctrine is that, with regard to prescription drugs, which are likely to be complex medicines, it is the prescribing physician who knows both the propensities of the drug and the susceptibilities of his patient, and who therefore is in the best position to prescribe a particular drug for the patient." *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179, 191, 766 N.E.2d 1118, 1126 (2002). Zimmer argues that there is even greater reason to apply the doctrine in the context of medical devices because while a patient "purchases and ingests [a prescription drug] on his or her own, a patient cannot use a medical device like the NexGen Flex without the active participation and exercise of judgment of the surgeon implanting it." (Def.'s Reply Mem. in Supp. of Summ. J. [129], 19.)

It is undisputed that the Wisconsin Supreme Court has not had the opportunity to address the issue of whether the learned intermediary doctrine is applicable under Wisconsin law. It is also undisputed that federal courts applying Wisconsin law have reached different conclusions about the doctrine's applicability. *Compare, e.g.*, *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (applying doctrine under Wisconsin law in case involving allegedly defective pedicle screw implants), *with Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968 (E.D. Wisc. 2009) (declining to apply doctrine in case involving prescription antidepressant drugs). The vast majority of states, however, do employ some version of the doctrine. *See Tyree v. Boston Sci. Corp.*, 56 F. Supp. 3d 826, 828 n.3 (counting

thirty-five states (including the District of Columbia) in which the high court has adopted the doctrine or favorably cited its application and an additional thirteen states (including Wisconsin) in which state intermediate courts or federal courts have applied the doctrine or predicted that the highest state court would adopt it); *see also Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 963 (E.D. Wis.), *amended,* 532 F. Supp. 211 (E.D. Wis. 1981) (applying the intermediary doctrine under Wisconsin law and stating that as "a general rule the courts of this country universally" apply the doctrine). In addition, this court's research suggests that those courts that have declined to apply the doctrine under Wisconsin law have done so in cases involving prescription drugs, not medical devices, and those courts offer no reason to believe that the Wisconsin Supreme Court would *not* adopt this majority rule if presented with the issue. *See Maynard v. Abbott Labs.*, No. 12-C-0939, 2013 WL 695817, at *5 (E.D. Wis. Feb. 26, 2013) (stating, without explanation, in a case involving a drug prescribed for treating arthritis that "Wisconsin does not apply the learned intermediary doctrine"); *Forst*, 602 F. Supp. 2d at 968 (declining to apply the doctrine without some indication that the Wisconsin Supreme Court would do so and where deciding question of doctrine's applicability was unnecessary to determine the outcome); *Peters v. AstraZeneca, LP*, 417 F. Supp. 2d 1051, 1054 (W.D. Wis. 2006) (declining to "create Wisconsin law" by adopting doctrine in case involving drug prescribed for treatment of acid reflux).

In the context of TKR surgery, a patient must rely on the experience and judgment of his or her surgeon, who selects the appropriate implant and educates the patient about the particular risks—based on the patient's particular circumstances and physiology—that accompany the selected implant or TKR surgery in general. Given that context, and given the widespread acceptance of the doctrine throughout the country, the court believes it is likely that the Wisconsin Supreme Court would apply the learned intermediary doctrine in this case.

2. Causation

If, as the court concludes above, the learned intermediary doctrine applies in this case,

then to the extent Zimmer had a duty to warn about the risks of its device or to provide proper surgical instructions, its duty was to warn Joas's implanting surgeon. In this case, Dr. Larson, the implanting surgeon admits that he has never read the package insert that accompanied Joas's implant and that he still had not read the insert as of the day he was deposed. (Larson Dep. 83:24–84:24.) And although he testified that he read "parts of" Zimmer's surgical technique guide years before performing Joas's surgery, Dr. Larson says that he learned the technique he used to implant the device "from [his] fellowship and training" and did not rely on any printed or written material from Zimmer. (*Id.* 85:1–86:13.) Because Dr. Larson did not read or rely upon the warnings Zimmer actually provided, Plaintiffs cannot prove that an improved warning—whether about the risks of high-flexion activities or about proper surgical technique—would have led to a different outcome in Joas's case.

Plaintiffs asserted at oral argument that Wisconsin law recognizes a "heeding presumption," meaning that courts presume that the relevant actor would have read and abided by a proper warning. But Plaintiffs cite to no Wisconsin case law recognizing such a presumption, and the court has found conflicting opinions from Wisconsin appellate courts which have addressed the issue. *Compare Tanner v. Shoupe*, 228 Wis. 2d 357, 381, 596 N.W.2d 805, 818 (Ct. App. 1999) (allowing failure-to-warn claim to proceed though plaintiff admitted that he did not read warning on automobile battery that exploded), *with Kurer v. Parke, Davis & Co.*, 272 Wis. 2d 390, 409, 679 N.W.2d 867, 876 (Ct. App. 2004) ("A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury."). Under the rule stated in *Kurer*, Plaintiffs' failure-to-warn claims would fail because Plaintiffs have presented no evidence that either Dr. Larson or Joas himself would have altered their behavior in light of a change to Zimmer's package insert or surgical instructions. And though *Tanner* would seem to suggest that Plaintiffs have a viable failure-to-warn claim whether or not Dr. Larson read and relied upon Zimmer's warnings, that case is distinguishable from this one. In *Tanner*, the

plaintiff's failure to read the product's warning label was not fatal to his failure-to-warn claim because the fact-finder could assume that *other users* would have read the warning, which could have presented his injury. *Tanner*, 228 Wis. 2d at 379–80, 596 N.W.2d at 817. The court in *Tanner* concluded that an adequate warning could have alerted prior, third-party users of an automobile battery that it was dangerous to pound on the battery's vent caps, and that the lack of pounding could have prevented the plaintiff's injury whether or not he himself read and abided by the battery's warning. 228 Wis. 2d at 381, 596 N.W.2d at 818. There is no such argument in this case—that is, no contention that an improved warning would have prevented Joas's injury because someone other than Joas or Dr. Larson would have read it. And even if Plaintiffs are correct that Dr. Larson's admission that he did not rely upon the warning labels is not fatal to their failure-to-warn claims, those claims fail for other reasons. Plaintiffs cannot succeed on a failure-to-warn theory based on the absence of a warning about engaging in high-flexion activities because, as discussed above, they have not established that high-flexion activities caused the tibial component of Joas's knee implant to loosen. And Plaintiffs cannot succeed on a theory based on failure to instruct about proper cementing technique for the lack of expert testimony on that issue, as discussed below.

3. Lack of Expert Testimony

The court has already identified two defects in Plaintiffs' failure-to-warn theories—namely, the lack of expert testimony demonstrating that any aspect of Joas's device itself was the cause of his injury and the lack of evidence to show that an improved warning would have led to a different outcome for Joas's knee. The court also notes an additional problem with Plaintiffs' theory that Zimmer failed to provide adequate instructions about proper cementing technique: None of Plaintiffs' experts opine that Zimmer's Surgical Technique Guide was inadequate. As noted, Plaintiffs' own expert, Dr. Fetto, has ruled out improper surgical technique as a cause of Joas's knee failure and was willing to testify that there was "adequate cement" (Fetto Dep. 302:23), that "the surfaces of the components were covered with cement"

(*id.* at 303:17–18), and that he "[does not] think [he] saw anything that [he] felt was a significant deficiency in the cement technique or anything that would cause [him] concern about the cement techniques." (*Id.* at 304:1–5.) In an apparent about-face, Plaintiffs now attempt to rely on the testimony of Zimmer's expert, Dr. Dearborn, to establish that Dr. Larson did not in fact use an adequate amount of cement to affix Joas's device to his bone. But although it is true that Dr. Dearborn believes that at least two bags of cement should be used to implant the NexGen Flex device, nowhere in his expert report or his deposition testimony does he opine that it is Zimmer's responsibility to instruct surgeons on the appropriate number of cement bags to use in surgery. On the contrary, he states in his expert report that proper surgical technique is something surgeons learn as part of their basic medical training (Dearborn Rep. at 18), and Dr. Larson confirmed that he himself learned the surgical technique he used during his medical fellowship and training. (Larson Dep. 85:13–86:6.) Which aspects are part of a surgeon's basic training and which—if any—must be included in a medical device's accompanying instructions is not an issue "within the realm of the ordinary experience of mankind," and expert testimony is required to support a failure-to-warn claim on that theory. *Kandutsch*, 2011 WI 78, ¶ 28, 336 Wis. 2d at 491.

D. Punitive Damages

Because Plaintiffs cannot establish their other claims, their claim for punitive damages must also fail. *Hanson v. Valdivia*, 51 Wis. 2d 466, 474, 187 N.W.2d 151, 155 (1971) ("[A] claim for punitive damages alone is not sufficient to support a cause of action."); *Duvall v. Ford Motor Co.*, 91 Wis. 2d 848, 284 N.W.2d 120 (Ct. App. 1979) ("A separate cause of action for punitive damages does not exist.").

III. Potential Differences Between Joas's Case and Others in this MDL

Although the first bellwether case in this MDL proceeded to trial, this second one terminates at the summary judgment stage. There are a number of significant differences, however, between Joas's case and *Batty* that explain the different outcomes in the two cases,

and differences between Joas's case and future bellwether cases are likely to allow those cases, like *Batty*, to go before a jury as well. Unlike this case, the specific causation theory in *Batty* did not rely on a differential etiology. Instead, there was significant radiographic evidence that appeared to link Ms. Batty's injury with the plaintiffs' general causation theories. Proving causation via differential etiology in a case like this may be difficult because of the many possible causes of aseptic loosening that would have to be ruled out. But a properly applied differential etiology, with consistent standards for ruling causes in and out, may well provide an adequate specific causation opinion.

This case also differs from *Batty*, and possibly from other cases, in that Wisconsin law requires a proposed safer alternative design as an element of a design defect claim. In states where there is no such requirement, a design defect case may be easier to make. Also unlike in *Batty*, only Joas's tibial implant exhibited loosening. A causal link between the implant's design and femoral loosening, as in *Batty*, may be easier to establish. And finally, unlike in this case, there was evidence in *Batty* that the plaintiff's implanting surgeon had read the device's package insert and had relied upon information from Zimmer in selecting the device and warning his patients. Under such circumstances, a failure-to-warn claim becomes much more tenable.

CONCLUSION

For the reasons stated above, the court grants Zimmer's motion to exclude the testimony of Dr. Fetto [31] and grants Zimmer's motion for summary judgment [37] on all counts. The trial date is stricken.

ENTER:

Dated: October 21, 2016

REBECCA R. PALLMEYER
United States District Judge